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on September 18, 2006

Date of Deposit

Jasper W. Dockrey, Reg. No. 33,868

Name of applicant, assignee or
Registered Representative



Signature
September 18, 2006

Date of Signature

Case No. 1391/1555
Wrigley No. MAGBAR 01

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:

MAXWELL et al.

Serial No.: 10/606,671

Filing Date: June 25, 2003

For: BREATH FRESHENING AND
ORAL CLEANSING PRODUCT
WITH MAGNOLIA BARK
EXTRACT

Examiner:
Ruth A. Davis

Group Art Unit No.:
1761

DECLARATION UNDER 37 C.F.R. § 1.132

Mail Stop Amendment
Commissioner for Patents
P.O. Box 1450
Alexandria, Virginia 22313-1450

Dear Sir:

Declarant, Minmin Tian hereby declares as follows:

1. I am presently employed as a Senior Technology Scientist by Wm. Wrigley, Jr. Company at the Wrigley Global Innovation Center in Chicago, IL. I hold a PhD. degree in Chemistry from the University of Texas at Austin, Texas, which was awarded in December, 1994. Following graduating from the University of Texas, I was a Post Doctorial Fellow at the University of California-Berkely until June, 1996. Since then, I have worked as a research scientist at three major U.S. oral care product companies. I have held my current position at Wm. Wrigley, Jr. Company since December, 2003.
2. In my capacity as a technology scientist at Wm. Wrigley, Jr. Company, I have investigated a variety of botanic extracts for germ-kill, oral care, and breath freshening applications. I have investigated ingredients that help to maintain tooth plaque pH above 5.7, the critical pH that causes tooth demineralization. I have also studied various natural and synthetic compounds that are active against oral bacteria through a variety of in vitro microbiological testing methods as well as in vivo clinical trials. Furthermore, I have worked with confectionery formulations including breath films, compressed mints, hard and soft candies, and chewing gums. I have recently led a project directed to discovering, identifying, and developing magnolia bark extract for germ-kill, breath freshening, and oral care applications.
3. I have reviewed U.S. Patent Application No. 10/606,671, titled “BREATH FRESHENING AND ORAL CLEANSING PRODUCT WITH MAGNOLIA BARK EXTRACT.” I have also reviewed the Office Action of April 24, 2006 and the prior art references cited in the Office Action. In particular, I have reviewed PCT application publication No. WO 02/43657 to Barlalow et al., PCT application publication No. WO 01/85116 to Sherl et al., Japanese application publication No. JP357085319 to Nanba et al. (English abstract only), and U.S. Pat. No. 6,740,332 to Zyck et al. In addition, I have reviewed the patent claims presented in the response that accompanies this Declaration.

4. I consider myself to be a person skilled in the art in the subject matter disclosed and claimed in U.S. Patent Application No. 10/606,671 (“the ’671 application”). I have been asked to give opinions on the matters recited in this Declaration and I believe that I am qualified by education and experience to do so.

5. The edible film according to the invention described in the ’671 application delivers a very low total amount of magnolia bark extract (“MBE”) per unit dose compared to mouthwashes or dentifrices described in the prior art. Specifically, the ’671 application describes MBE levels as low as 0.005% by weight. (See for example, para. 0032). Despite these low levels of MBE, the edible films of the invention surprisingly provide antimicrobial efficacy in the oral cavity.

6. I base my opinion, in part, upon testing of edible films prepared according to the ’671 application. A pullulan-free edible film was prepared in accordance with the edible film formulations described in the ’671 application by others at the Wrigley Global Innovation Center. Table 1 below shows the ingredients and the ingredient concentrations for the edible film. The edible film, which weighed about 46 mg a piece, contained 0.21mg of MBE or 0.45 wt.% MBE.

Table 1. Example of a pullulan-free edible film according to the invention

Compound	Dry conc. %	Amount delivered per dosage (mg)
Na-alginate	30.13	13.86
Maltodextrin	28.24	12.99
Carrageenan corn dextrin	10.15	4.67
Peppermint flavor	8.53	3.92
Microcrystalline cellulose	8.35	3.84
Glycerin	7.56	3.48
Menthol	3.59	1.65
Lectin	1.31	0.60
Intense sweetener	1.16	0.53
Magnolia Bark Extract	0.45	0.21
Colorant	0.36	0.17
Citric acid	0.17	0.08
Total	100.00	46.00

I am aware that the pullulan-free edible film described above was evaluated for germ-kill effect by a clinical trial. The clinical trial involved 236 subjects. In the clinical trial, the edible film demonstrated surprisingly strong germ-kill effect up to 20 minutes and 40 minutes after consumption. One dosage was found to reduce total bacteria counts by 49% at 20 minutes and 34% at 40 minutes.

7. As shown in Table 1 above, the amount of MBE delivered per dosage of the edible film was 0.21mg of MBE or 4500 ppm. The total germ kill effect with this low dosage of antimicrobial agent is surprising because a 34% to 49% reduction in total bacterial count would only be expected in edible films containing pullulan.

8. Based on existing patents and other literature sources, it is widely believed that pullulan is a polymeric material that operates to enhance the efficacy of antimicrobial agents. For example, the effect of pullulan is explained in the excerpt of U.S. Pat. No. 6,923,981 reproduced below.

"A further aspect of this invention is that while the amounts of LISTERINE® essential oils are relatively high for incorporation in a film, the film according to the present invention still delivers a lower total amount of essential oils per unit dose when compared to that of LISTERINE® mouthwash. Yet the film surprisingly provides antimicrobial efficacy in the oral cavity. The inventors theorize that the preferred film forming ingredient, pullulan, forms a thin layer on the oral surfaces entrapping the small amount of essential oils which are capable of penetrating into the pits and fissures of the oral cavity to provide sustained antimicrobial efficacy." (U.S. Pat. No. 6,923,981, Col. 4, ll. 4-14)

As stated in the excerpt above, pullulan is thought to be a film forming material that binds to oral surfaces and entraps small amount of germ-kill actives capable of penetrating into the pits and fissures of the oral cavity to provide sustained antimicrobial efficacy. Accordingly, it was believed to be necessary to include pullulan in an edible film in order to obtain germ kill efficacy with a relatively low concentration of antimicrobial agent in the edible film.

9. In view of the general understanding of the action of pullulan in edible films, I find it surprising that, in the invention of the '671 application, a pullulan-free combination of sodium alginate, maltodextrin, carrageenan, micro-crystalline cellulose, and a low level of MBE, provide effective germ-kill against bacteria that cause bad breath. In the invention described in the '671 application, the amount of MBE delivered to oral cavity is below 1 microgram. This amount of antimicrobial agent is much less than would be expected necessary in a pullulan-free edible film that was effective at killing germs causing bad breath.

10. Despite the role of pullulan described in the prior art, based on the results of my testing, I conclude that sodium alginate, maltodextrin, carrageenan, micro-crystalline cellulose and other ingredients in combination with MBE in the particular proportions of the invention provide an effective film forming polymer that binds to oral surfaces and entraps a small amount of MBE. This combination provides a sustained anti-microbial effect even with exceedingly small amounts of MBE.

11. In contrast to the invention described in the '671 application, the Sherl et al. reference describes dentifrice compositions that contain a combination of Triclosan and the phenolic compounds magnolol and honokiol from Magnolia Extract. In

Example II of Sherl et al., an oral care composition is described containing 0.3% MBE and 0.3% triclosan. (Sherl et al., Table II, composition B, pg. 11). As shown in Table 2 below, I have calculated the total amount of MBE delivered to oral cavity by the composition of Example IIB to be about 3mg (based on an average dentifrice dosage of 1g).

Table 2. Example II B of Scherl et al.

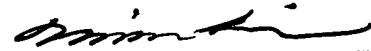
Compound	conc. %	Amount delivered per dosage (mg)
D.I. Water	15.807	158.07
Glycerin	20	200
Carboxymethyl cellulose	1.10	11
Carrageenan	0.4	4.0
Sodium Saccharine	0.3	3.0
Sodium fluoride	0.243	2.43
Titanium dioxide	0.5	5
Noncrystallizing sorbitol	20.85	208.5
Gantrez S-97	15	150
Silican abrasive	20	200
Silicon thickener	1.5	15
Flavor	1.0	10
Sodium hydroxide 50%	1.2	12
Magnolia Bark Extract	0.30	3.0
Triclosan	0.30	3.0
SLS	1.5	15
Total	100.00	1000

The amount of MBE in the composition of Sherl et al. shown above is 14 times higher than that of the edible film composition prepared in accordance with the invention of the '671 application and as set forth above in paragraph 6.

12. Although the Sherl et al. reference describes MBE concentrations ranging from 0.001-50% in an oral care dentifrice, I believe that such dentifrices cannot achieve germ-kill efficacy at a level of MBE below 1 mg per dosage without the presence of Triclosan.
13. Given the description in the prior art of the function of pullulan in edible films and the MBE concentrations necessary for effective germ kill in dentifrices, the results of the pullulan free edible film described in the '671 application is surprising. Accordingly, I do not believe that the invention described and claimed in the '671 application is obvious in view of the a dentifrice containing MBE as taught by Sherl et al. or Nanba et al. and the pullulan-free edible film described by Barlalow et al. or the edible films described by Zyck et al.
14. It is my further opinion that one skilled in the art would be aware of the amount of MBE delivered to the oral cavity based on the description of the invention provided in the '671 application. As shown above, I calculated the amounts delivered per dosage for both the pullulan-free edible film described in the '671 application and the composition described by Sherl et al. One skilled in the art, upon reading the '671 application would be able to readily determine the amounts of MBE delivered to the oral cavity of a user as I have done above.
15. I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code.

September 12, 2006

Date



Minmin Tian